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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,951	02/24/2004	Daniel Henry Densham	GJE-35D1	5474
23557	7590	11/06/2006		
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
			EXAMINER SISSON, BRADLEY L	
			ART UNIT 1634	PAPER NUMBER

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/786,951

Applicant(s)

DENSHAM, DANIEL HENRY

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 14 August 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 7,008,766 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of sequencing DNA as set forth at pages 14-15 of the specification, does not reasonably provide enablement for the sequencing of non-DNA targets, the sequencing of multiple targets simultaneously, the use of a plurality of nucleotides simultaneously, and the sequencing of any target, regardless of composition and length, where no blocking moieties are present on the nucleotides and where the incorporated nucleotide is detected by a means other than the exploitation of pulsed monochromatic light, or where nucleotides are not flowed into and out of a reaction/fluidic cell, or where data is not collected electronically. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

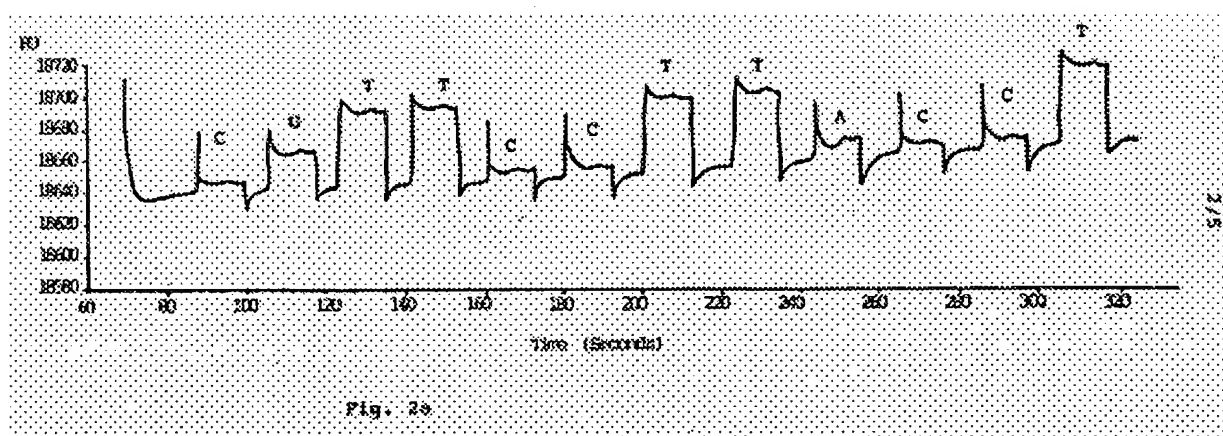
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4. For purpose of examination, the method of claim 1 has been interpreted an encompassing the determination of any length of polynucleotide, including full-length chromosomes. Said method has also been interpreted as encompassing the simultaneous sequencing of an infinite number of polynucleotides that are present in a single mixture.

5. The claimed method has also been interpreted an encompassing both direct and indirect immobilization of any polymerase on any solid support. Such language has been further construed as to encompass the binding of the polymerase to a target polynucleotide, where the target polynucleotide is directly or indirectly bound to the solid support.

6. The claimed method has also been construed as encompassing the determination of the complete nucleotide sequence where no blocking step is performed, and where all possible nucleotides are present in a given mixture, thereby allowing for full length transcripts.

7. Of the examples provided, that found at page 14, bridging to page 15 of the disclosure is most relevant to the claimed method. As set forth therein the results obtained are presented in Figure 2. For convenience, Fig. 2a is reproduced below.



8. It is evident from the disclosure, including Fig. 2a, that the but a single template was being sequenced, an then the nucleotide sequence was determined at a rate of about 1 nucleotide

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per 20 seconds. Significantly, but a single nucleotide was incorporated into the complementary strand at a time, and that further nucleotide addition was proscribed due to the presence of a blocking group in the 3' position.

9. As presently worded, the method can be practiced without any blocking groups on the nucleotides to be incorporated, and that all of the nucleotides can be present simultaneously, and that there not be any need for a label or other means for identifying the incorporated nucleotide(s). Conversely, the specification does not set forth a reproducible procedure whereby dual blocking groups are present and are selectively removed.

10. Indeed, as presently worded, the method of claim 1 fairly encompasses having a plurality of targets present as well as four different nucleotides, and that the reaction not be limited in any manner. Clearly, the specification does not teach real-time sequencing where nucleotides are identified at the rate of their incorporation into a nascent nucleic acid strand.

11. In contrast to the claimed method, the specification teaches explicitly at page 15, "[o]nce the 3' blocking group has been released from the polymerized nucleotide, further polymerization may occur." Such language, as well as the use of a chip, beta-dimer, flowing nucleotide reagents into and out of a reaction cell, and pulsed monochromatic light, clearly speak to and enable a much different invention. Applicant is urged to consider amending the claims to where they more closely parallel the invention set forth in the original disclosure.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

13. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

14. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 11, 12, 16, 17, 21, and 22 of copending Application No. 10/478,036. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a method of sequencing a polynucleotide.

16. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Response to argument

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18. Argument is presented at page 7 of the response of 14 August 2006 that the claimed method is not obvious as the method of the '036 application requires "measurement of a non-linear optical signal or a linear signal coupled to a non-linear signal."

19. The above argument has not been found persuasive for while the method of claim 1 of the instant application does require "measuring a change in or absorption of radiation that occurs during the interaction," the claimed method of the instant application is sufficiently broad so as to encompass the limitations recited in the '036 application. Accordingly, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

20. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS